

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

U.S. DISTRICT COURT
DISTRICT OF VERMONT
FILED

2020 JAN 27 AM 11:03

UNITED STATES OF AMERICA,

v.

Docket No.

CLERK
BY BY
DEPUTY CLERK

PRACTICE FUSION, INC.,
Defendant.

2:20-cr-11-1

INFORMATION

The United States Attorney charges:

I. INTRODUCTION

1. Beginning in or around fall 2013 Defendant PRACTICE FUSION solicited remuneration from a pharmaceutical company (“Pharma Co. X”) in exchange for creating and embedding an alert, known as a clinical decision support (“CDS”) alert, in PRACTICE FUSION’s electronic health record (“EHR”) to prompt doctors to take certain clinical actions in order to increase prescriptions of Pharma Co. X’s extended release opioids (“EROs”). Once implemented, this CDS alert (“the Pain CDS”) caused doctors to focus on assessing and treating a patient’s pain symptoms, and supplied healthcare providers a list of potential care plan treatment options. The Pain CDS suggested treatments, including opioids, without regard to the medical appropriateness of each option.

2. The remuneration offered and paid by Pharma Co. X and solicited and received by PRACTICE FUSION in return for PRACTICE FUSION designing the Pain CDS with a purpose of increasing Pharma Co. X’s ERO sales, portions of which were paid for by federal health care programs, was a kickback in violation of 42 U.S.C. § 1320a-7b(b)(1) & (b)(2).

3. PRACTICE FUSION and Pharma Co. X's agreement and acts in furtherance of their unlawful kickback scheme was a conspiracy to violate the Anti-Kickback Statute, in violation of 18 U.S.C. § 371.

II. BACKGROUND

At times relevant to this Information:

4. "Pharma Co. X" (a pseudonym) was a United States-based pharmaceutical company whose products included branded extended release opioids.

5. Defendant PRACTICE FUSION was a Delaware corporation with headquarters in San Francisco, California. PRACTICE FUSION was a cloud-based EHR company that generally provided its cloud-based EHR product to healthcare providers without charge.

6. Employee #1 was a PRACTICE FUSION Life Sciences Sales Representative initially in charge of the Pharma Co. X account.

7. Employee #2 was PRACTICE FUSION's Senior Vice President for Life Sciences Practice and Strategic Partnerships.

8. Employee #3 was PRACTICE FUSION's Chief Commercial Officer ("CCO"), and later Chief Executive Officer ("CEO").

9. Employee #4 was PRACTICE FUSION's Chief Medical Officer.

10. Employee #5 was PRACTICE FUSION's Director of National Accounts and was ultimately responsible for the Pharma Co. X account at the time the Pain CDS deal closed. Employee #5 was the Practice Fusion employee credited with closing the Pain CDS deal and the only employee who received a commission in connection with the deal.

11. Employee #6 was PRACTICE FUSION's Director of Strategic Development, Life Science Partnerships.

12. Pharma Co. X Employee #1 was Pharma Co. X's Director of eMarketing.
13. Pharma Co. X Employee #2 was a Pharma Co. X Brand Manager in charge of one of Pharma Co. X's ERO brands.
14. Pharma Co. X Employee #3 was a Pharma Co. X physician.
15. PRACTICE FUSION provided EHR services to tens of thousands of active healthcare provider users in the United States, including in Vermont, and its software was used during millions of patient encounters each month.
16. Though PRACTICE FUSION offered its EHR to healthcare providers free of charge, PRACTICE FUSION had various sources of revenue. Federal regulations provided for the implementation of CDS alerts in EHR software. Practice Fusion derived revenue from this clinical functionality in the form of payments from pharmaceutical companies in exchange for creating and implementing CDS alerts in its EHR.
17. PRACTICE FUSION's CDS alerts typically worked as follows for a healthcare provider using the PRACTICE FUSION EHR: a message would appear on the PRACTICE FUSION EHR alerting the healthcare provider that, given the particular personal health information and circumstances of the patient before the provider at that moment, the provider should consider certain clinical information, perform certain tests or assessments, and complete certain documentation.
18. PRACTICE FUSION understood that pharmaceutical companies would pay for the CDS because the CDS could boost sales of the pharmaceutical companies' products.
19. PRACTICE FUSION understood that Pharma Co. X provided remuneration in exchange for the Pain CDS because the CDS could boost sales of Pharma Co. X's ERO products.

20. PRACTICE FUSION understood that it was unlawful to sell CDS programs based on anticipated returns on investment that a pharmaceutical company client could achieve through the CDS, and that any CDS program must be consistent with any applicable evidence-based medical guidelines and Department of Health and Human Services (“HHS”) Centers for Medicare and Medicaid Services (“CMS”) Clinical Quality Measures (“CQM”).

21. Extended release opioids are highly addictive narcotics that are properly prescribed only in limited circumstances. According to labeling for Pharma Co. X’s leading ERO, that product was indicated “for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” The ERO’s labeling moreover directed: “Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release formulations, reserve [Pharma Co. X’s ERO product] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.”

22. The FDA-approved labeling states that Pharma Co. X’s primary ERO was “[t]o be prescribed only by healthcare providers knowledgeable in use of potent opioids for management of chronic pain.”

23. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) prohibited PRACTICE FUSION from knowingly and willfully soliciting or receiving remuneration in return for “arranging for or recommending” ordering any good or item for which payment may be made in whole or in part under a Federal health care program. PRACTICE FUSION knowingly and

willfully violated the Anti-Kickback Statute through its solicitation and receipt of remuneration from Pharma Co. X in connection with the Pain CDS.

24. 18 U.S.C. § 371 prohibits conspiracies and provides that “[i]f two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.” PRACTICE FUSION conspired with Pharma Co. X to violate the Anti-Kickback Statute through its solicitation and receipt of remuneration from Pharma Co. X in connection with the Pain CDS.

III. PRACTICE FUSION SOLICITED REMUNERATION FROM PHARMA CO. X IN RETURN FOR A CDS THAT WOULD ARRANGE FOR AND RECOMMEND THE ORDERING OF EXTENDED RELEASE OPIOIDS

25. PRACTICE FUSION began discussing the prospect of using its EHR in furtherance of Pharma Co. X’s marketing goals with Pharma Co. X personnel as early as fall 2013. These discussions included the possibility of using the PRACTICE FUSION EHR to screen potential patients for whether they were suitable for long-term opioid therapy, including assessing whether the patient had a history of substance abuse.

26. PRACTICE FUSION and Pharma Co. X did not pursue a CDS alert to assist doctors in screening patients for risk of opioid abuse; instead, they developed a CDS to increase sales of Pharma Co. X’s ERO products.

27. As discussions between the parties increasingly focused on Pharma Co. X’s commercial objectives, Employee #1 was counseled in an internal PRACTICE FUSION email in April 2014 that “[i]ndicating that [Pharma Co. X] influenced clinical decisions through sponsored

money has legal implications versus a marketing program where a banner can be displayed and influence a prescribing behavior.”

28. In or around May 2014, PRACTICE FUSION continued its solicitation of Pharma Co. X by forwarding to Pharma Co. X news stories concerning PRACTICE FUSION’s implementation of a CDS program paid for by a vaccine manufacturer. The article was forwarded within Pharma Co. X to its Chief Executive Officer with the message: “I know you know of Practice Fusion, we too are working to get our pain management tools into their platform.” Pharma Co. X’s CEO responded, “Thanks. The key is understanding how it grows or protects scripts.”

29. Between May 2014 and March 2015, representatives from PRACTICE FUSION and Pharma Co. X continued to communicate regularly regarding potential transactions between the two companies.

30. In a March 23, 2015 internal PRACTICE FUSION email—written in preparation for a scheduled March 31, 2015 meeting at Pharma Co. X—Employee #1 described the opportunity to sell a CDS program to Pharma Co. X by explaining to PRACTICE FUSION colleagues that Pharma Co. X “has communicated that the average dosage of [Pharma Co. X’s leading ERO] is declining” and that “[p]roviders are hesitant about using high dosages to combat pain for a variety of reasons, mostly, political pressure.” The email further stated that “[a]s a result, [Pharma Co. X] is toying with the idea of using Pain Assessment tools with the provider at every visit and before every RX.” RX is an abbreviation for prescription.

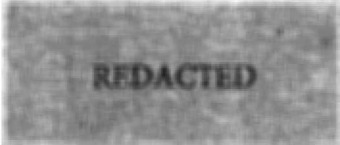
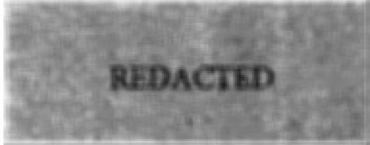

31. PRACTICE FUSION understood Pharma Co. X was concerned that as a result of heightened public awareness of the dangers of opioid use, healthcare providers were prescribing lower dosages of opioids. PRACTICE FUSION thus marketed its medical software as having

the potential to influence provider behavior and counteract Pharma Co. X's economic concerns regarding providers prescribing fewer and lower dosages of opioids.

A. PRACTICE FUSION'S MARCH 31, 2015 SOLICITATION TO PHARMA CO. X AND ENSUING FOLLOW-UP SOLICITATIONS

32. On or about March 31, 2015, PRACTICE FUSION representatives travelled to Pharma Co. X's headquarters to continue soliciting payment from Pharma Co. X in exchange for a CDS. PRACTICE FUSION's solicitation materials included a PowerPoint presentation, commonly referred to as a "pitch deck." PRACTICE FUSION's pitch deck indicated that a pain CDS would be "based on" the "brand objectives" of Pharma Co. X's three extended release opioid products. These objectives included targeting "opioid naïve patients"—i.e., patients who were not previously prescribed opioids—and targeting patients who were using immediate release opioids ("IROs"). A slide from the pitch deck depicting Practice Fusion's understanding of Pharma Co. X's brand objectives is excerpted below:

Brand Objectives

		
<ul style="list-style-type: none">▪ Target: Opioid Naïve Patients▪ Patients that cannot be controlled▪ Patients that cannot tolerate certain Opioids▪ Individually Titrate▪ How-to Use 2 patches of similar strengths, for example, two 7.5 mcl/hour patches▪ Patient Savings Card program	<ul style="list-style-type: none">▪ Target: Oxycodone IR patients▪ Individualize does per patient▪ Pain Assessment at every visit▪ Titrating Therapy▪ Abuse Deterrent Formulation▪ Patient Savings Card program	<ul style="list-style-type: none">▪ Target: Hydrocodone IR patients▪ FDA Approved Tier 1 and Tier 3 Abuse Deterrent labeling▪ Once/Day dosing▪ Titrate to individual patient needs▪ Perform Pain Assessment at every visit▪ Patient Savings Card Program

33. Pharma Co. X advised PRACTICE FUSION that it wished to utilize a CDS to “target” the opioid naïve and IRO users. Those patients represented potential additional users of Pharma Co. X’s EROs. Further, Pharma Co. X would make more money selling its drugs if PRACTICE FUSION’s CDS helped “keep[] an appropriate patient on a consistent dose” PRACTICE FUSION thus recommended creating a CDS alert to address Pharma Co. X’s concerns.

34. While PRACTICE FUSION and Pharma Co. X employees used euphemisms like “appropriate patients,” “identify care gaps,” and “better manage patients,” both parties understood a goal of the program was to increase ERO use. As described *infra*, the parties did not ensure “appropriate” patients received EROs.

35. Following the March 31, 2015 presentation, Employee #2 emailed Employee #3 stating that “next steps” with respect to the Pharma Co. X solicitation included “build[ing] [a] model to show potential commercial impact of increased patients being screened for pain and risk of opioid abuse.”

36. According to this March 31, 2015 email, the PRACTICE FUSION personnel who were to “model” the “commercial impact” to Pharma Co. X’s drug sales from the CDS included: Employee #1, Employee #4, Employee #5, and Employee #6.

37. Employee #5 modelled the “commercial impact” that would accrue to Pharma Co. X as a result of the Pain CDS causing an increase in ERO prescriptions. PRACTICE FUSION calculated that Pharma Co. X would obtain a return on investment (“ROI”) of between 5.8 and 7.8 times its cost if it implemented the PRACTICE FUSION Pain CDS.

38. A version of the model estimated that Pharma Co. X would achieve a “patient gain” of two thousand seven hundred seventy-seven (2,777) and between \$8,458,232 and \$11,277,643 in additional opioid revenue by implementing the CDS.

39. PRACTICE FUSION developed a model to show the “commercial impact” to Pharma Co. X of a pain CDS, and Pharma Co. X eventually entered into a contract with PRACTICE FUSION for the Pain CDS based on the parties’ mutual expectation of increased ERO sales.

40. An April 1, 2015 internal PRACTICE FUSION email, containing an early version of the “commercial impact” model is excerpted below, showing that PRACTICE FUSION sought to align its EHR with the commercial objectives of Pharma Co. X:

We could use these values to present an economic benefit of the proposed program in three ways or any additional suggestions.

1. Value of keeping an appropriate patient on a consistent dose of one of the products throughout the 2 year term of the program
2. Value of conversion from IR to ER and consistent dosing over the term of the program
3. Value of a % market share in the branded ERO space; █████ mentioned they enjoy an 83% share in the branded ERO space. We can track and measure two things during the program. Share of the current branded EROs on our platform and potential new market entrants to ERO therapy as a result of the clinical intervention

During our planning call, we can work with █████ to help develop outcomes measures that can map back to these metrics.

41. PRACTICE FUSION solicited remuneration from Pharma Co. X to design the Pain CDS to cause healthcare providers to extend the duration of ERO prescriptions, convert patients receiving IROs to EROs, to increase the overall market of ERO-using patients, and to measure its ability to deliver such results.

42. In an April 22, 2015 internal PRACTICE FUSION email discussing follow up communications to Pharma Co. X, Employee #5 advised: “Since this is being sent to a marketing audience the idea of ROI has to be part of the plan to justify the costs of the program.”

Employee #5 further inquired “[d]o you think we can develop some sort of ROI model that can make assumptions of increased patient volumes or increased persistency on these products to calculate an estimated ROI?”

43. It is common in the healthcare industry for pitch decks to be scrutinized for purposes of ensuring legal and regulatory compliance. PRACTICE FUSION did not include its calculations of increased opioid patient volume, increased opioid sales, or increased persistency to opioid products in the pitch materials provided to Pharma Co. X. Rather, on or about April 23, 2015, Employee #5 directed in an internal PRACTICE FUSION email pertaining to the Pharma Co. X CDS written proposal: “Don’t include the ROI in the proposal. We’ll walk the client through the ROI.”

44. On April 28, 2015, Employee #2 described the final Pharma Co. X pitch deck as “concise and will allow us to voice over what we need to regarding how the program works and its commercial impact.” Practice Fusion “voiced over” the “commercial impact” of the program, rather than describe it in the pitch deck, because it knew and understood that CDSs should not be sold to pharmaceutical clients on the basis that the CDS could influence doctors’ prescribing in ways commercially beneficial to the sponsoring pharmaceutical client.

45. On April 29, 2015, Employee #2 stated in an internal email referring to the Pharma Co. X CDS proposal that “[t]he goal here is to sell it as a study-but get commercial\$ moved over or added to the funding to make the deal work.” This same email observed that there was “urgency” for PRACTICE FUSION to generate revenue.

46. On May 11, 2015, Employee #6 asked Employee #5 if he had “the final pricing model you used for [Pharma Co. X]?” Employee #6 then wrote: “Actually...without saying

ROI...I mean the ROI spreadsheet ;-).” Employee #5 then provided the Pharma Co. X ROI analysis.

B. PRACTICE FUSION’S SEPTEMBER 1, 2015 PRESENTATION AT PHARMA CO. X HEADQUARTERS AND SUBSEQUENT FOLLOW-UP

47. Employee #5 emailed personnel in Pharma Co. X’s marketing department on July 16, 2015, “to re-engage around the Practice Fusion Clinical Decision Support Real World Evidence Pain Management program.” He stated “[w]e feel that the proposed program can help meet the strategic commercial needs of the pain franchise at [Pharma Co. X.]”

48. Prompted by the July 16, 2015 email described in the preceding paragraph, PRACTICE FUSION and Pharma Co. X’s marketing personnel scheduled an additional presentation at Pharma Co. X’s headquarters for PRACTICE FUSION to propose the Pain CDS program in greater detail. This meeting was scheduled for September 1, 2015, at Pharma Co. X’s headquarters.

49. On or about July 30, 2015, Pharma Co. X’s Executive Director for Marketing sent an email to Pharma Co. X Employee #1 (Pharma Co. X’s Director of eMarketing) advising that the Brand Managers in charge of two of Pharma Co. X’s three ERO brands “can benefit” by attending the upcoming meeting with PRACTICE FUSION at which the Pain CDS proposal would be presented.

50. On or about August 17, 2015, Employee #5 discussed PRACTICE FUSION’s proposal with two Pharma Co. X employees, Pharma Co. X Employee #1 and Pharma Co. X Employee #2. In an email describing that discussion, Employee #5 stated that PRACTICE FUSION’s “proposed solution” would include, among other features, “appropriate pain assessment tools/screeners that will help providers in the decision to initiate ERO products,” and “[u]nbranded clinical messaging to reinforce appropriate use of EROs in patient populations —

IRO users, chronic NSAID users, tramadol, etc.” This email further explained that Pharma Co. X Employee #1 desired to see a “draft strategy by weeks end to discuss and refine for presentation to the broader commercial team during [the] meeting in Sept.”

51. On or about August 21, 2015, Employee #5 forwarded a preliminary version of the September 1, 2015 presentation to Pharma Co. X Employee #1.

52. On or about September 1, 2015, two PRACTICE FUSION employees, including Employee #5, travelled to Pharma Co. X’s headquarters to propose that Pharma Co. X pay PRACTICE FUSION approximately \$1,000,000 to develop and implement the Pain CDS to influence health care providers to prescribe more EROs.

53. Pharma Co. X marketing personnel representing each of its three ERO brands attended the September 1, 2015 presentation. The presentation included a pitch deck in which PRACTICE FUSION proposed the CDS program focus on the treatment of pain by: “Leverag[ing] Practice Fusion Platform to deliver Clinical Decision Support and measure the impact and real world outcomes on patient care”; delivering “clinical patient-centric provider messages” targeted at healthcare providers with “opioid naïve patients with chronic pain,” and with patients currently receiving immediate release oxycodone and hydrocodone; and “Leverag[ing] the Practice Fusion EMR platform to help providers assess, diagnose, and treat Chronic Pain.”

54. The proposal also included PRACTICE FUSION providing “educational messages” targeted to healthcare providers with patients with diagnoses of “chronic pain and with history of non-Opioids in their chart.”

55. The proposed Pain CDS would prompt the provider to assess the patient’s pain, and to “evaluate conversion rates from IR opioid or chronic pain non opioid treatment to ERO.”

56. Employee #5 led discussion of the Pain CDS at the September 1, 2015 in-person proposal.

57. Pharma Co. X employees understood based on the presentation that the Pain CDS would keep pain top of mind and influence physicians to switch more patients from non-opioids and IROs to Pharma Co. X's EROs. Marketing personnel within Pharma Co. X also liked that the proposed Pain CDS allowed Pharma Co. X to, in essence, be present in the exam room while they interacted with patients.

58. After the September 1, 2015 meeting, a PRACTICE FUSION employee provided the pitch materials by email on September 2, 2015 to the PRACTICE FUSION employee who advised Employee #1 regarding the legal implications of using a CDS as a marketing tool, as described in paragraph 27 above. That employee in turn forwarded those materials to another PRACTICE FUSION employee by email with a message that included: "I understand that the [Pharma Co. X] proposal has shifted to a commercial focus and that marketing folks were in the room instead of outcomes[.]" The message also included "[t]here are several things incorrect with this presentation/proposal from pricing to products. Please do not share. Just be aware...."

59. The September 1, 2015 pitch materials were forwarded within PRACTICE FUSION because of concerns about how Employee #5 had sold the CDS alert to Pharma Co. X, including discussions surrounding how the CDS would grow Pharma Co. X's opiate sales.

60. PRACTICE FUSION included a "study" as part of the September 1 proposal. A September 2 internal PRACTICE FUSION email observed, however, that Pharma Co. X was not interested in a study: "we were talking to product managers, and they could care less about RWE [real world evidence]. For them, this was all about marketing." The email further stated that during the September 1 meeting with Pharma Co. X "I made it clear that we would measure

success (metrics, switches from IR to ER, etc.).]” The study was included in the proposal, in part, to make the deal appear as a legitimate medical project, and not a commercial endeavor.

61. A September 1, 2015 internal PRACTICE FUSION email from Employee #5 confirmed that Pharma Co. X’s “brands” would contribute equally to the cost of the program “since this is a non branded effort.”

62. On September 4, 2015, Employee #5 emailed Pharma Co. X Employee #1 a “revised deck” that was “based on our meeting this week.” This “revised deck” included a new slide devoted to “Project Goals” (excerpted below). Those goals included (among others): “Educate providers around appropriate patients for ERO therapy”; “Identify care gaps through clinical decision support alert tools at the point of care”; “Aid providers in identifying patients who are experiencing pain and prompt corrective action or change in therapy”; and to provide Pharma Co. X a “[d]etailed analysis of effectiveness of clinical decision support alerts on treatment patterns (focus on IR/non opioid to ERO conversion) and outcomes (quarterly metrics).”

Project Goals

- + Educate providers around appropriate patients for ERO therapy
- + Identify care gaps through clinical decision support alert tools at the point of care
- + Aid providers in identifying patients who are experiencing pain and prompt corrective action or change in therapy
- + Create or enhance pain score capture and functional assessment data
- + Provide to [REDACTED] detailed data and analytics
 - Detailed process metrics (quarterly metrics)
 - Detailed analysis of current market landscape and treatment patterns (one time deliverable)
 - Detailed analysis of effectiveness of clinical decision support alerts on treatment patterns (focus on IR/non opioid to ERO conversion) and outcomes (quarterly metrics)
- + Produce a published peer reviewed manuscript

IV. PRACTICE FUSION RECEIVED REMUNERATION FROM PHARMA CO. X IN RETURN FOR A PAIN CDS THAT WOULD ARRANGE FOR AND RECOMMEND THE ORDERING OF EXTENDED RELEASE OPIOIDS

63. Shortly after the September 1, 2015 meeting, Pharma Co. X and PRACTICE FUSION moved forward with designing the Pain CDS as pitched by PRACTICE FUSION.

64. In September and October 2015 Pharma Co. X marketing personnel integrated the PRACTICE FUSION Pain CDS proposal into their internal 2016 Marketing Tactic presentations. According to internal Pharma Co. X documents, the objective of the program was to “Grow ERO prescriptions within the Practice Fusion ehr [electronic health record],” by using the PRACTICE FUSION platform to cause providers to “reassess chronic pain patients for the need for Extended Release Opioids.” Pharma Co. X identified the “strategic pillar” of the Pain CDS as “Portfolio Tactic – Grow the ERO market” and described the program as “[a]lerts for patients with chronic pain will occur at the point of prescription.”

65. In a document titled Marketing Portfolio Budget Review, Pharma Co. X noted that “[p]romotion within an EMR may help to grow ERO market and [Pharma Co. X] products” and that Pharma Co. X would “achieve” an “[i]ncrease[d] awareness and usage of ER Opioids by educating providers around appropriate patients for ERO therapy” (emphasis in original).

66. Moreover, the document stated that the partnership with PRACTICE FUSION would “*drive ERO demand thru EMR Patient Messages*” (emphasis in original). A portion of that slide is depicted on the following page:

Promotion within an EMR may help to grow ERO market and products

What Is It?

- Develop a **partnership with Practice Fusion eHR to help manage chronic pain** patients by targeting Pain Specialists and PCPs and **drive ERO Demand thru EMR Patient messages**



What We Will Do?

- Leverage existing Chronic Pain Quality Measures to **reassess chronic pain patients for the need for Extended Release Opioids**

67. In an internal September 10, 2015 Pharma Co. X email sent to marketing personnel working on each of Pharma Co. X's ERO brands, Pharma Co. X Employee #1 noted "Practice Fusion estimates a high ROI of 5 to 1 but I think we should be more conservative going into this program for the first time in order to under promise and over deliver."

68. Attached to that email was a Pharma Co. X summary of the PRACTICE FUSION proposal that listed the "KPI" [key performance indicator] of the Pain CDS as: "Increase in ERO prescribing." The summary also estimated that the Pain CDS would cause 22,500 patients to switch to EROs. Based on Pharma Co. X's share of the branded ERO market, Pharma Co. X estimated that it would obtain a favorable 2 to 1 return on its approximately one million dollar investment in the Pain CDS. A later, more conservative calculation estimated the program would return 1.31 to 1.

69. The PRACTICE FUSION CDS project received internal Pharma Co. X approval in or around late 2015. Each of Pharma Co. X's three ERO brands contributed equal amounts from their marketing budgets to fund the marketing project. Pharma Co. X brand representatives agreed to provide PRACTICE FUSION the remuneration because they understood that the Pain CDS would increase sales of its EROs.

70. Shortly after authorizing the Pain CDS arrangement, beginning in late 2015 and continuing in early 2016, Pharma Co. X Employee #1 and PRACTICE FUSION personnel began designing a CDS alert to proliferate ERO prescriptions.

71. Pharma Co. X Employee #1 and PRACTICE FUSION personnel—including Employee #4 and Employee #5—worked together to design the Pain CDS alert. Employee #5 and Pharma Co. X Employee #1 reviewed the draft Pain CDS from PRACTICE FUSION’s clinical personnel and proposed edits that would enhance the likelihood that the Pain CDS would increase prescriptions.

72. For example, a January 29, 2016 email from Pharma Co. X Employee #1 to Employee #5 included a proposed edit to the Pain CDS workflow that allowed healthcare providers to “check off ‘Extended Release Opioid initiated’ – by adding this we think this will trigger the prescriber to assess again if a change in therapy is needed as a follow up.” Pharma Co. X Employee #1 was a marketing employee and had no expertise in treating a patient’s pain or prescribing opioid medications and was not a physician.

73. Before signing off on the project, Pharma Co. X’s head of marketing required a mockup of the CDS alert. Pharma Co. X Employee #1 wrote to Employee #5: “see the request below from my boss. I think if we show him the workflow documents with ERO message added that should do it for him.” Employee #5 revised the proposed workflow “to reflect extended release opioid as a treatment option for a finding of pain during the initial assessment.”

74. As implemented, “long acting/extended release” opioids were referenced parenthetically in the care plan portion of the Pain CDS as one of the treatment options for providers to select.

A. THE PAIN CDS CONTRACT

75. PRACTICE FUSION and Pharma Co. X entered into a written statement of work (“SOW”) contracting for the Pain CDS effective March 1, 2016, in which they agreed to, among other things: provide health care providers “who utilize the Practice Fusion Solution” with a CDS Program “directed at chronic pain management treatment with immediate release opioids and chronically used NSAIDs” that would “support the identification of and/or treatment of patients who are recommended to be screened for or receive the treatments specified in” what the contract described as “gold standard evidence-based clinical guidelines” that were attached to the contract. The SOW attached Clinical Quality Measure #131, which called for healthcare providers to prepare “documentation of a follow-up plan when pain is present” for patients over 18 years old “with documentation of a pain assessment using a standardized tool(s).”

76. The contract specified that Pharma Co. X “shall be the funding source for the CDS Program.”

77. In the contract, Pharma Co. X and PRACTICE FUSION agreed that Pharma Co. X would pay PRACTICE FUSION \$144,600 for a “Retrospective Analysis” and \$815,100 for CDS-related work.

78. Despite the parties’ mutual understanding that the purpose of the Pain CDS program was to increase ERO prescriptions, the contract stated that the “Parties agree and acknowledge that the collaboration project will follow national evidenced-based guidelines, and will not encourage the prescribing or utilization of a [Pharma Co. X]-specific product or services.”

79. The contract also called for PRACTICE FUSION to target “awareness messages” about the Pain CDS at healthcare providers who prescribed NSAIDs and IROs.

80. Pursuant to the parties' SOW, PRACTICE FUSION and Pharma Co. X were to "participate in an initial RWE Study kick-off meeting" and "[d]uring the course of the RWE Study, regular meetings will be held between [Pharma Co. X] and Practice Fusion teams to review progress on the RWE Study and the Project work plan. These meetings, which will be scheduled at RWE Study kick-off will enable continued attention to RWE Study tasks and deliverables." After the contract was agreed to, Employee #5 described the program as an "exciting use of EMR technology."

V. PHARMA CO. X AND PRACTICE FUSION DESIGN THE PAIN CDS

81. Notwithstanding the SOW provision that the Pain CDS "will not encourage the prescribing or utilization of a [Pharma Co. X]-specific product or services," a written internal PRACTICE FUSION recap of the initial conference call between PRACTICE FUSION and Pharma Co. X to design the project confirmed that the "success" of the Pain CDS program would be "increased prescriptions for [Pharma Co. X's] meds APPROPRIATELY (EROs in general and specifically [Pharma Co. X's])." Another summary, circulated within both companies stated "Primary goal of the project is to increase Rx for [Pharma Co. X.'s] medications," and also noted that while there would be no specific pharmacotherapy intervention as part of the CDS program, the prescribing of EROs "will likely be one of the follow-up plans when pain scale is high."

82. Contemporaneous to the development of the commercially-focused Pain CDS, on or about March 15, 2016, the United States Centers for Disease Control and Prevention ("CDC") published the "CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016" ("CDC Guidelines"). Shortly after the CDC Guidelines were released, they were circulated within both Pharma Co. X and PRACTICE FUSION, including among those involved in developing the Pain CDS.

83. Both PRACTICE FUSION and Pharma Co. X employees involved in creating the Pain CDS—including physicians Employee #4 and Pharma Co. X Employee #3—possessed and reviewed the CDC Guidelines during development of the Pain CDS. However, the parties did not incorporate the recommendations contained in those guidelines into the CDS.

84. The CDC Guidelines stated, among other things:

- a. extended release opioids “should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week”;
- b. “When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids”;
- c. “When opioids are started, clinicians should prescribe the lowest effective dosage”;
- d. “Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient”;
- e. “The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent”; and
- f. Providers should “[b]e explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term

use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely.”

85. In or about April 2016, Pharma Co. X personnel requested that the Pain CDS include opioids as a treatment option in addition to treatments identified within a 2016 New England Journal of Medicine (“NEJM”) article entitled “Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies.” That article admonished, among other things, that it was not intended to provide clinical instruction in the treatment of chronic pain, and that the benefits of opioids for treatment of chronic pain were “much more questionable” than for treatment of acute pain.

86. Similar to the CDC Guidelines, the NEJM article identified concerns about overdosing and abuse by patients and “Factors associated with the risk of opioid overdose or addiction,” which included, among other things:

- a. Daily dosages greater than 100 MME [morphine milligram equivalents];
- b. Long-acting or extended-release formulation;
- c. Combination of opioids with benzodiazepines;
- d. Long-term opioid use (greater than 3 months);
- e. Depression;
- f. Substance-use disorder; and
- g. History of overdose.

87. The NEJM article further provided a table of “Mitigation Strategies against Opioid Diversion and Misuse.” These strategies included, among other things:

- a. Screening tools to identify patients with a substance-use disorder, such as the Opioid Risk Tool; the Screener and Opioid Assessment for Patients with Pain (SOAPP); the Brief Risk Interview;
- b. Use of data from the Prescription Drug Monitoring Program;
- c. Use of Urine Drug Screening; and
- d. Doctor-patient agreement on adherence.

88. Despite reviewing and purportedly relying on the NEJM article in developing the Pain CDS, Pharma Co. X and PRACTICE FUSION did not design the Pain CDS to address any of the factors listed above as risks of opioid overdose and addiction; nor did the parties incorporate any of the “Mitigation Strategies against Opioid Diversion and Misuse.” Both Employee #4, and Pharma Co. X Employee #3 possessed and reviewed both the NEJM article and CDC Guidelines; nonetheless, both physicians signed off on the Pain CDS despite their knowledge that the program had been commercially conceived, funded by opiate brand managers, and did not incorporate the above-referenced guidelines designed to curb opioid abuse.

89. Pharma Co. X marketing personnel remained involved in designing the Pain CDS at the time the NEJM article was selected and incorporated into the Pain CDS.

90. Indeed, Pharma Co. X marketing personnel, who lacked expertise in administering or prescribing opioids, were involved in decisions relating to key functionalities of the Pain CDS, including use of the Pain Score, use of the BPI, the contents of the Care Plan options, the guidelines and CQM on which the Pain CDS was purportedly based, and the CDS logic. As evidenced below, personnel from Pharma Co. X’s marketing teams remained involved in numerous aspects of designing the CDS:

- a. An April 8, 2016 internal Pharma Co. X email confirming that the eMarketing Director—not a physician—had “decided with the marketing team to use the BPI [brief pain inventory].”
- b. An April 8, 2016 internal Pharma Co. X email noting that “There are no guidelines that support teasing out chronic vs acute pain.”
- c. An April 11, 2016 email confirming that the Director of eMarketing was involved in defining chronic pain for purposes of the Pain CDS.
- d. An April 14, 2016 email between two Pharma Co. X physicians and the Director of eMarketing suggesting the Pain CDS care plan include options supported by the NEJM article “plus opioids?” Less than an hour later Pharma Co. X wrote PRACTICE FUSION that it was “noodling on” the “care plan.” The email was sent by a Pharma Co. X doctor to PRACTICE FUSION and Pharma Co. X’s Director of eMarketing.
- e. An April 26, 2016 internal Pharma Co. X email noting that the Director of eMarketing “needs to sign off” on the CDS Clinical Logic.

91. In a document dated April 5, 2016 [excerpted on the following page], Pharma Co. X Employee #3 listed “Concerns” relating to the Pain CDS, which included, among other things: “BPI can increase ERO use”; “Can’t look as if we are directing information or therapy”; and “Program must be retrospective in nature – it can not [sic] look as if we are causing a change in Rx.”

Concerns:

- Is this a STUDY or is a MARKETING project? Different issues depending on the answer.
- No mention of consent
- No mention of IRB
- Data collected just to see if BPI influences actions around Rx or Tx
- BPI can increase ERO use
- If data collected, can it be used for promotional work by MSLs or Reps down the road?
- No discussion of long term outcomes, no discussion of patient follow up for additional study
- Can't look as if we are directing information or therapy
- Program must be retrospective in nature - it can not look as if we are causing a change in Rx.
- What is the sample size possible with this study? Can we do a pre-look for possible responders and users of PHR
- Will there be sufficient responders? What is the in-silico possible response rate?
- Ask EHR co about use rates of their Portal by Pts - and other programs with response rates
- If this is done by Marketing, it CAN'T look like a study - if it's a STUDY it MUST be run by Medical
- Need more thought about outcomes and what we'd want to see from this.

92. On May 11, 2016, a PRACTICE FUSION employee reported on a call with Pharma Co. X personnel about the development of the CDS and observed that he kept "hearing the client [Pharma Co. X] revert back to 'Rx lift' as the primary objective of the program, this came up in the kickoff meeting and again during last week's meeting when we were talking about the objectives of the prospective and retrospective analyses." "Rx lift" refers to increased prescriptions. The email is depicted below:

Hi [REDACTED]

I wanted to make sure that the two of you are aligned with your respective stakeholders in terms of what the goals of the [REDACTED] pain program are. I keep hearing the client revert back to "Rx lift" as the primary objective of the program, this came up in the kickoff meeting and again during last week's meeting when we were talking about the objectives of the prospective and retrospective analyses. [REDACTED] seems to be championing this vision as the new commercial + analytics stakeholder.

During the last meeting [REDACTED] mentioned that the goals of the analytic project were to "meet all marketing science objectives, and whatever other HEOR objectives we can get to" which does not at all align with the analytic plan the client already "approved". Please let me know if I should setup some time for us to strategize internally here.

93. Despite knowledge that the Pain CDS was conceived with the intent of increasing Pharma Co. X's drug sales, that Pharma Co. X marketing personnel participated in the design of the Pain CDS, that marketing personnel had selected the BPI to be used, and that the BPI could

increase ERO usage during a time of great national concern around opioid abuse, Practice Fusion and Pharma Co. X nonetheless proceeded with implementing the CDS to broaden use of EROs.

94. Moreover, the Pain CDS program was not “run by medical” as the document referenced in paragraph 91 conceded it “MUST” be if the program were a study. As detailed, *infra*, Pharma Co. X’s marketers remained involved throughout the design and implementation even after the Pain CDS went live and continued to inquire and assess whether it achieved their stated goal of influencing ERO prescribing.

VI. THE PAIN CDS IN OPERATION IN DOCTORS’ OFFICES ACROSS THE COUNTRY

95. The CDS program went live on PRACTICE FUSION’s platform in early July 2016. As finalized, the Pain CDS contained three separate alerts. The first alert encouraged healthcare providers to record a pain score. The second alert suggested that doctors take a BPI of patients who had recorded two or more pain scores of four or more (on a zero to ten-point scale) within the previous three months, or who had a chronic pain diagnosis. The BPI further focused providers on the patient’s pain symptoms and included a list of questions on the severity and impact of the patient’s pain, and prompted the patient to describe the patient’s pain “now,” “on the average,” and at its “worst” and “least” during the previous 24 hours. The third alert indicated that a follow up plan should be created for treating the patient’s pain, appearing only if the patient reported pain on the pain scale of four or higher twice within four months, or if a patient with chronic pain has had a BPI completed.

96. Pharma Co. X anticipated that prompting doctors to assess and re-assess pain would increase ERO prescriptions.

97. The CDS utilized a drop-down menu of options for pain treatments to populate the treatment plan. This menu listed the following options, alphabetically, each on equal footing:

The screenshot shows a software interface for a 'FOLLOW-UP PLAN'. At the top, there is a search bar containing the text 'Surgical' and a magnifying glass icon. Below the search bar is a list of treatment options, each on a new line. The options are: Adjuvant pharmacotherapy (e.g. topical agents, antispasmodics), Biofeedback, Education (e.g. reassurance; exercise; appropriate activities), Interventional or neural stimulation therapy, Nonopioid analgesics (e.g. acetaminophen; NSAIDs; antidepressants), Nonpharmacologic (e.g. physical therapy; cognitive-behavioral therapy), Opioid Therapy (short-acting, long-acting/extended release), Pain resolved, Referral to pain specialist, and Surgical Procedure.

FOLLOW-UP PLAN

Surgical

Adjuvant pharmacotherapy (e.g. topical agents, antispasmodics)

Biofeedback

Education (e.g. reassurance; exercise; appropriate activities)

Interventional or neural stimulation therapy

Nonopioid analgesics (e.g. acetaminophen; NSAIDs; antidepressants)

Nonpharmacologic (e.g. physical therapy; cognitive-behavioral therapy)

Opioid Therapy (short-acting, long-acting/extended release)

Pain resolved

Referral to pain specialist

Surgical Procedure

98. As implemented, the Pain CDS alert deviated from medical guidelines in several respects, including:

- a. the Pain CDS's list of treatment options was in part sourced from the NEJM medical journal article that was not intended to address how to treat patients with chronic pain;
- b. in addition to the non-opioid analgesics and other alternative pain-treatment options identified by the NEJM article, PRACTICE FUSION and Pharma Co. X added "Opioid Therapy (short-acting, long-acting/extended release)" as a treatment option within the care plan

without regard for whether the patient's condition was indicated for either immediate or extended release opioids in that:

- i. EROs are listed as an option for patients with less than severe pain;
 - ii. EROs appeared as an option for patients with pain without regard to whether "alternative treatment options were ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain";
 - iii. EROs were suggested as a treatment option for patients whose pain was not around-the-clock, but who presented with separate complaints of acute pain within three months.
- c. The Pain CDS instructed providers to record a treatment plan only when pain was classified as "chronic" or was above a certain threshold over a period of time. The CQM's performance standards required providers to record a treatment plan any time the pain assessment was documented as positive.
 - d. The Pain CDS did not incorporate recommendations from the CDC Guidelines and did not incorporate the substance of the NEJM article from which the CDS sourced a list of treatment options.
 - e. The Pain CDS listed EROs as a treatment option on equal footing with IROs and non-opioid therapy—contrary to accepted medical practice.
 - f. The Pain CDS listed EROs as an option for patients who had not previously received opioid therapy (i.e., the opioid naïve).

99. The Pain CDS also listed EROs as a treatment option without regard to whether the provider had the adequate expertise to prescribe EROs.

100. In sum, the value to Pharma Co. X of increased referrals arranged by the Pain CDS was used to justify the remuneration provided; the CDS was not consistent with guidelines such as the CDC Guidelines and NEJM article; the CDS was inconsistent with the applicable CQM; the CDS was funded by Pharma Co. X's marketing department; and Pharma Co. X's drug marketers were involved in its design.

A. AFTER IMPLEMENTATION PRACTICE FUSION AND PHARMA CO. X CONTINUED TO VIEW THE PAIN CDS AS A COMMERCIAL PROGRAM

101. After the Pain CDS went live in doctors' EHRs across the country, Pharma Co. X continued to view the program as a commercial venture. In or about October 2016, internal Pharma Co. X marketing emails inquired when Pharma Co. X would see an analysis of the commercial impact of the Pain CDS. The Director of eMarketing responded that he was not sure whether Pharma Co. X would be allowed to perform such an analysis "in this environment."

102. On October 7, 2016, Pharma Co. X's Director of Marketing sent an email to brand representatives, corporate executives, and the Director of eMarketing with the subject line: "immediate action tactics to appropriately grow NTRx [i.e., new prescriptions] during Q4." In this context, "Q4" refers to the fourth quarter of Pharma Co. X's fiscal year.

103. On October 12, 2016, a document titled "Urgent Tactics" with a list of "HIT Ideas" was sent in response to the request for "immediate action tactics to appropriately grow NTRx." It stated, "Have the Analytics Group look at the Practice Fusion Pain Guideline Pilot data available to date to get an early read on the effectiveness of the Clinical Decision Support alerts on improving the pain management of members of the test group of HCPs [health care providers] vs.

the control group.” In this context, “improving pain management” was thus equated with growing new total prescriptions.

104. PRACTICE FUSION and Pharma Co. X planned an in-person meeting at Pharma Co. X’s headquarters to report on a retrospective study and the results of the Pain CDS. PRACTICE FUSION was instructed to answer whether “the CDS alerts change prescribing behavior” and “show ERO prescribing as it tracks with CDS.” Pharma Co. X continued to have an interest in understanding whether, and by what measure, the Pain CDS was achieving its intended goal of influencing ERO prescribing in ways commercially favorable to Pharma Co. X’s drug sales.

105. On or about December 14, 2016, PRACTICE FUSION personnel conducted the presentation at Pharma Co. X’s headquarters. During this meeting, PRACTICE FUSION reported that through November 30, 2016, the Pain CDS had alerted during 21 million patient visits, involving 7.5 million patients, and 97,000 healthcare providers. During this presentation PRACTICE FUSION explained:

- a. that since Pain CDS alerts went into effect “there is a general shift toward EROs from IROs”; and
- b. the “biggest shift [was] within Emergency Medicine, Orthopedics, and Pain Medicine.”

106. PRACTICE FUSION’s presentation included charts and graphs that depicted the relative share of IROs vs. EROs as prescribed by doctors utilizing the PRACTICE FUSION EHR since the Pain CDS went into effect.

107. PRACTICE FUSION also analyzed the effectiveness of various pain treatment options, including adjuvants, COX-2s, EROs, IROs, and NSAIDs, finding that overall EROs were the least effective in lowering pain as only 39.17% of patients treated with EROs had lower pain, as shown in the chart below from the December 14, 2016 presentation (emphasis added):

Pain Score Summary								
Adjuvant	Change (#)	Change (%)	COX-2	Change (#)	Change (%)	ERO	Change (#)	Change (%)
Lower Pain	3,022	41.96%	Lower Pain	394	47.30%	Lower Pain	805	39.17%
No Change	1,707	23.70%	No Change	195	23.41%	No Change	611	29.73%
Higher Pain	2,473	34.34%	Higher Pain	244	29.29%	Higher Pain	639	31.09%

IRO	Change (#)	Change (%)	NSAID	Change (#)	Change (%)
Lower Pain	3,622	46.31%	Lower Pain	5,647	45.45%
No Change	1,818	23.24%	No Change	2,724	21.93%
Higher Pain	2,382	30.45%	Higher Pain	4,053	32.62%

108. Similarly, PRACTICE FUSION's data found that EROs were the second least effective treatment option in lowering pain among patients with chronic pain (emphasis added):

Pain Score Summary (Chronic Pain)								
Adjuvant	Change (#)	Change (%)	COX-2	Change (#)	Change (%)	ERO	Change (#)	Change (%)
Lower Pain	547	40.22%	Lower Pain	53	47.75%	Lower Pain	259	40.41%
No Change	329	24.19%	No Change	30	27.03%	No Change	185	28.86%
Higher Pain	484	35.59%	Higher Pain	28	25.23%	Higher Pain	197	30.73%

IRO	Change (#)	Change (%)	NSAID	Change (#)	Change (%)
Lower Pain	626	42.33%	Lower Pain	576	40.88%
No Change	399	26.98%	No Change	375	26.61%
Higher Pain	454	30.70%	Higher Pain	458	32.51%

109. PRACTICE FUSION additionally provided data and information to Pharma Co. X identifying the "Top Diagnosis Groups" that received EROs. Pharma Co. X did not take any

steps in connection with the Pain CDS to ensure that EROs were being prescribed to “appropriate” patients, let alone consistent with the CDC Guidelines or NEJM article.

110. A Pharma Co. X attorney was present at the December 14, 2016 meeting. The attorney expressed reservations about the Pain CDS, noting that it had not received appropriate legal review within Pharma Co. X, and considered “pausing” the program.

111e Rather than pausing the program, the Pain CDS program continued. In a series of emails from December 2016 and January 2017, Pharma Co. X requested PRACTICE FUSION supply materials related to the Pain CDS for the purposes of Pharma Co. X’s legal review.

112. Employee #5 gathered the materials to be provided to Pharma Co. X for this belated legal review. The materials provided for this purpose did not disclose the commercial objective of the program.

113. The Pain CDS was not “paused” or modified to be consistent with medical guidelines. Instead, the parties allowed the Pain CDS alerts to continue. As had been initially contemplated during the proposal process, PRACTICE FUSION and Pharma Co. X prepared a poster detailing the “results” of the Pain CDS that was presented at a public symposium. The parties’ presentation concluded, among other things, that a CDS can “help physicians follow chronic pain management clinical guidelines and improve documentation of care-related data and activity.” While the poster observed that “[d]ocumentation of opioid therapy in care plans shifted from 33.1% at start to 20.2% at conclusion,” the parties did not include an analysis of actual opioid prescribing trends—as opposed to care plan documentation—and did not assess ERO prescribing. The presentation demonstrated that it caused a large increase in the number of patients having care plans recorded; approximately 4,800 to 6,300 more care plans per month were completed in association with the Pain CDS than by providers who did not receive the

alerts. Moreover, the parties did not reveal in this presentation that a goal of the Pain CDS was to increase ERO prescribing, that Pharma Co. X's marketers were involved in designing the program, that the Pain CDS was financed by marketing budgets, or whether the Pain CDS influenced prescribing of EROs.

B. THE PAIN CDS INCREASED PRESCRIPTIONS OF EXTENDED RELEASE OPIOIDS, INCLUDING PHARMA CO. X'S EROs

114. The Pain CDS alert was live on the PRACTICE FUSION platform from early July 2016 to the spring of 2019. The Pain CDS alerted more than 230,000,000 times during this period. Physicians wrote hundreds of thousands of ERO prescriptions after one of the Pain CDS alerts had been triggered.

115. Healthcare providers who received the Pain CDS alerts prescribed EROs at a higher rate than those that did not.

116. Based on the higher rate of opioid prescriptions among providers who received the Pain CDS, the alerts resulted in tens of thousands of additional prescriptions for EROs, a substantial portion of which were paid for by federal healthcare programs such as Medicare and Medicaid.

COUNT ONE

117. Paragraphs 1 through 116, are realleged and incorporated herein.

118. Beginning not later than 2015 and continuing to an unknown time but not earlier than June 30, 2017, in the District of Vermont and elsewhere, PRACTICE FUSION knowingly and willfully conspired, in violation of 18 U.S.C. § 371, with Pharma Co. X, and others known and unknown to the United States Attorney, to solicit, and receive remuneration in return for recommending and arranging for the ordering of extended release opioids, including Pharma Co. X's products, with such orders being paid for in whole or in part under a Federal health care program, in violation of 42 U.S.C. § 1320a-7b(b)(1) & (b)(2).

Manner and Means of the Conspiracy

The manner and means by which PRACTICE FUSION and its co-conspirators sought to accomplish the objects and purpose of the conspiracy included, among others, the following:

119. In late 2015, PRACTICE FUSION asked for and Pharma Co. X agreed to pay PRACTICE FUSION almost \$1 million in exchange for PRACTICE FUSION altering its EHR in order to induce healthcare providers to prescribe ERO medications.

120. Employees of PRACTICE FUSION modeled the estimated return on investment that Pharma Co. X could realize if it paid PRACTICE FUSION for the proposed Pain CDS.

121. PRACTICE FUSION justified the price Pharma Co. X paid for the CDS based upon PRACTICE FUSION's return on investment calculations that estimated the increase in Pharma Co. X ERO prescriptions that would result from the Pain CDS.

122. Pharma Co. X decided to pay PRACTICE FUSION's price by reference to Pharma Co. X's anticipated increase in ERO prescriptionse

123. Following September 1, 2015, PRACTICE FUSION and Pharma Co. X personnel regularly communicated in order to collaborate on the design, approval, and execution of the Pain CDS.

124. On or about March 1, 2016, PRACTICE FUSION and Pharma Co. X executed a written contract by which PRACTICE FUSION was to receive almost \$1 million from Pharma Co. X principally in exchange for implementing the Pain CDS.

125. PRACTICE FUSION and Pharma Co. X developed the Pain CDS without incorporating the most recent CDC-promulgated guidelines.

126. PRACTICE FUSION and Pharma Co. X developed the Pain CDS without incorporating the mitigating measures recommended by recent medical literature to reduce the risk of addiction and abuse.

127. PRACTICE FUSION and Pharma Co. X designed the Pain CDS to present EROs as a treatment option on equal footing with other treatments for pain without regard to whether EROs were medically appropriate for patients including whether the patient had around-the-clock pain.

128. PRACTICE FUSION and Pharma Co. X designed the Pain CDS to direct providers to prepare a pain treatment plan only for some patients, and not whenever pain is present, in contrast to the CQM upon which the Pain CDS was purported to be based.

129. From in or about July 2016 to in or about April 2019, PRACTICE FUSION maintained the Pain CDS on its EHR, resulting in the CDS alerting during more than 230,000,000 patient visits, prompting doctors to focus on the treatment of pain and suggesting opioids as a treatment option, when another option may have been medically appropriate.

Overt Acts

130. The following overt acts were committed in furtherance of the conspiracy:
- a. On or about March 31, 2015, Practice Fusion employees travelled to Pharma Co. X's headquarters in an effort to persuade Pharma Co. X to pay PRACTICE FUSION to implement a CDS alert on the PRACTICE FUSION platform;
 - b. PRACTICE FUSION personnel developed a model to estimate the return on investment that Pharma Co. X's ERO brands could be expected to receive in exchange for Pharma Co. X's sponsorship of the proposed Pain CDS;
 - c. PRACTICE FUSION personnel communicated the result of their model to Pharma Co. X in an effort to persuade Pharma Co. X to agree to the Pain CDS program;
 - d. On or about September 1, 2015, Practice Fusion employees travelled to Pharma Co. X's headquarters in an effort to persuade Pharma Co. X to pay PRACTICE FUSION to implement the Pain CDS on the PRACTICE FUSION EHR platform;
 - e. In or around September 2015, Pharma Co. X estimated the return on investment Pharma Co. X could expect to receive based on Pharma Co. X's sponsorship of the Pain CDS as proposed by Practice Fusion;
 - f. In or around September and October 2015, Pharma Co. X marketing personnel integrated the Pain CDS into their list of 2016 marketing tactics for internal Pharma Co. X consideration;

- g. In or around March 2016, agents from Pharma Co. X and PRACTICE FUSION executed a written contract pertaining to the Pain CDS project;
- h. From in or about December 2015 through June 2016, PRACTICE FUSION and Pharma Co. X personnel designed the Pain CDS logic;
- i. In or around March 2016, personnel from Pharma Co. X and PRACTICE FUSION had telephonic meetings to refine the CDS design, during which the financial objective of the Pain CDS was re-stated;
- j. In early July 2016, PRACTICE FUSION implemented the Pharma Co. X-sponsored Pain CDS on the Practice Fusion EHR platform;
- k. From in or about March 2016 through in or about March, 2017, Pharma Co. X paid PRACTICE FUSION approximately \$959,700 in exchange for PRACTICE FUSION's development and implementation of the Pain CDS;
- l. On or about December 14, 2016, employees from PRACTICE FUSION travelled to Pharma Co. X headquarters to present information about, among other things, the effect the Pain CDS was having on healthcare provider prescribing behavior;
- m. From in or about July 2016 until it was taken down in or about April 2019, PRACTICE FUSION maintained the Pain CDS alert on its EHR platform, resulting in the alert triggering during more than 230,000,000 patient visits.

(18 U.S.C. § 371)

COUNT TWO

131. The United States Attorney realleges paragraphs 1 through 130, and incorporates them herein.

132. From in or about late 2013 through March 2016, PRACTICE FUSION solicited remuneration from Pharma Co. X in return for utilizing PRACTICE FUSION's EHR to arrange for and recommend the ordering of EROs, including Pharma Co. X's ERO products, items for which payment may be made in whole or in part under a Federal health care program.

133. From in or about March 2016 through at least March 2017, PRACTICE FUSION received remuneration from Pharma Co. X in return for arranging for and recommending the ordering of EROs, including Pharma Co. X's ERO products, items for which payment may be made in whole or in part under a Federal health care program.

134. From in or about early July 2016 through in or about April 2019 in the District of Vermont and elsewhere the Pain CDS was live on PRACTICE FUSION's EHR and arranged for and recommended the ordering of EROs, including Pharma Co. X's EROs.

(42 U.S.C. § 1320a-7b(b)(1) & (b)(2))

FORFEITURE ALLEGATION

135. The allegations contained in and relied on in Counts One and Two of this Information are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Section 982(a)(7).


136. Upon conviction of the offense[s] in violation of Title 42, United States Code, Section 1320a-7b(b)(1) & (b)(2) and Title 18, United States Code, Section 371, set forth in Counts One and Two of this Information, PRACTICE FUSION shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense(s). The property to be forfeited includes, but is not limited to, \$959,700 in U.S. currency.

a. If any of the property described above, as a result of any act or omission of the defendant[s]:

- i. cannot be located upon the exercise of due diligence;
- ii. has been transferred or sold to, or deposited with, a third party;
- iii. has been placed beyond the jurisdiction of the court;
- iv. has been substantially diminished in value; or
- v. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

All pursuant to 18 U.S.C. § 982(a)(7) and 28 U.S.C. § 2461(c).

 (OCJF/MPD)
CHRISTINA E. NOLAN
United States Attorney
Burlington, Vermont
January 27, 2020